

REMARKS

Claims 61, 67, 69-72 and 74-84 were pending in the application. Claims 61, 74 and 81 have been amended. New claims 85-90 have been added.

Claims 61, 74 and 81 have been amended to remove reference to the “complement” of SEQ ID NO:1320. Claim 81 was further amended to correct an obvious typographical error by replacing “products” with “product”.

New claims 85-90 are also supported by the application as originally filed. For example, support for new claims 87 and 90 can be found at paragraphs [0065], [0085] and [0086].¹

No new matter has been added.

Upon entry of this amendment, claims 61, 67, 69-72 and 74-90 will be pending.

Withdrawn Rejections

Applicants thank the Examiner for the indication that several rejections set forth in the previous Office Action have been withdrawn. Specifically, the following rejections were withdrawn:

(1) rejection of claims 61, 67, 69-72 and 74-81 under 35 U.S.C. § 112, first paragraph – written description (NEW MATTER REJECTION);

(2) rejection of claims 61, 67, 69-72 and 74-81 under 35 U.S.C. § 112, first paragraph – written description;

(3) rejection of claims 61, 67, 69-72 and 80 under 35 U.S.C. § 102(b) as allegedly anticipated by Salomon et al. (Endocrine-Related Cancer 7: 199-226, 2000);

(4) rejection of claims 61, 67, 71, 72, 75, 76 and 80 under 35 U.S.C. § 102(b) as allegedly anticipated by Guc et al. (Eur. J. Haematol 64(1):3-9, January 2000);

(5) rejection of claims 61, 67, 69-72, 74-76, 80 and 81 under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent 6,569,662 (filed July 19, 2000).

¹ Paragraph numbering is as set forth in U. S. Published Patent Application US 2006-0194265 A1.

Rejection Under 35 U.S.C. §112, first paragraph – enablement

Claims 61, 67, 69-72 and 74-81 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Although acknowledging that the specification enabled methods:

for diagnosing lymphoma, carcinoma, breast cancer or colon cancer comprising detecting evidence of differential expression of complement receptor type 1 (CR1) gene in a patient sample, wherein evidence of differential expression is detected by measuring the level of an expression product of CR1 and wherein the expression product of CR1 is a mRNA having a sequence of SEQ ID NO:1320, wherein evidence of differential expression of the CR1 gene indicates that the patient has lymphoma, carcinoma, breast cancer or colon cancer,

the Office alleges that the specification does not “reasonably provide enablement for the said method measuring a full complement of the mRNA sequence of SEQ ID NO:1320 (CR1)” The Office alleges that a “protein encoded from the mRNA, based on the translation of the complementary sequence from 5’ to 3’, would not bear any resemblance to the protein encoded from SEQ ID NO:1320 and hence would not be applicable to the claimed method.” (Office Action, pages 3-4). Applicants respectfully traverse.

Notwithstanding the foregoing and solely in an attempt to advance the prosecution of the pending claims to allowance, Applicants have amended the pending claims. As amended, claims 61, 74 and 81 no longer recite a full complement of SEQ ID NO:1320. Claims 67, 69, 72 and 75-80 depend from claims 61, 74 and 81.

New claims 85-89 have been added. New claims 85 and 86 depend from claims 61 and 81, respectively, and recite the means by which levels of expression product are determined. Applicants respectfully assert that new claims 85 and 86 are in compliance with the enablement requirement.

New claims 87-90 provide methods of diagnosing lymphoma, leukemia, carcinoma, breast cancer or colon cancer based on a hybridization analysis. Specifically, claim 87 recites methods for diagnosing lymphoma, leukemia, carcinoma, breast cancer or colon cancer

comprising contacting a polynucleotide that hybridizes under highly stringent conditions to a nucleotide sequence comprising SEQ ID NO:1320 with nucleic acids of a patient sample under binding conditions suitable to form a duplex and comparing the amount of the duplex formed to the amount of duplex formed when the polynucleotide is contacted with nucleic acids of a normal, non-cancerous control. Increased levels of the amount of duplex formed upon contacting the polynucleotide with nucleic acids of the patient sample compared to the amount of duplex formed upon contacting the polynucleotide and nucleic acids of the normal non-cancerous control are indicative of the presence of lymphoma, leukemia, carcinoma, breast cancer or colon cancer in the patient. Claims 88 and 89 recite increased levels of the duplex in the patient sample relative to control indicative of cancer. Claim 90 recites stringent hybridization conditions.

Applicants respectfully assert that new claims 87-90 are also in compliance with the enablement requirement. The specification as filed teaches one of skill in the art how to measure and compare levels of nucleic acids. See, for example, paragraphs [0085] and [0086].

Accordingly, Applicants respectfully request withdrawal of the enablement rejection under 35 U.S.C. §112, first paragraph.

23362.0001; 20366-066001
SERIAL NO.: 10/669,920

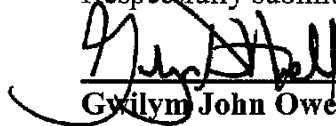
PATENT
FILED: September 23, 2003

Conclusion

The examination of the pending claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (302) 778-8458 to clarify any unresolved issues raised by this response.

Please apply any charges or credits to Deposit Account 06-1050 referencing Attorney Docket No. 20366-066001.

Respectfully submitted,



Gwilym John Owen Attwell
Registration No. 45,449

Date: September 4, 2007
Fish & Richardson P.C.
P.O. Box 1022
Minneapolis, MN 55440-1022
(302) 652-5070 telephone
(877) 769-7945 facsimile

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